IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

ABBVIE INC., ET AL., *Plaintiffs,* **VERSUS** **JEFFREY LANDRY, in his official capacity as Attorney General of Louisiana,** *Defendant.*	**CIVIL ACTION** **NO. 6:23-cv-01307** **JUDGE SUMMERHAYS** **MAGISTRATE JUDGE WHITEHURST**

ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

NOW INTO COURT, through undersigned counsel, comes Defendant, Jeff Landry, in his official capacity as Attorney General of Louisiana ("Defendant" or "Landry"), and, in response to the First Amended Complaint for Declaratory and Injunctive Relief filed by plaintiffs, AbbVie, Inc., Allergan, Inc., Durata Therapeutics, Inc., AbbVie Products, LLC, Aptalis Pharma US, Inc., Pharmacyclics, LLC, and Allergan Sales, LLC ("Plaintiffs"), Landry denies all allegations except those specifically admitted herein. With full reservation of rights and applicable defenses, Defendant Landry further responds to the allegations of Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief in like-numbered paragraphs as follows:

PRELIMINARY STATEMENT

1. The allegations in Paragraph 1 asserting the unconstitutionality of Act 358 are denied. To the extent the allegations in Paragraph 1 consist of Plaintiffs' characterizations of this

action and conclusions of law, no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 1 are denied in their entirety.

2. The allegations of Paragraph 2 consist of Plaintiffs' characterizations of federal law, characterizations of Congressional actions and intent, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 2 are denied. Answering further, the federal 340B statute does not provide for a comprehensive program – the statute contains no provisions governing the manner by which 340B drugs are distributed to the patients of covered entities, contains many gaps, and does not compel any particular outcome on the use of contract pharmacies by covered entities. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Contract Pharmacy Services, 61 Fed. Reg. 43,549 (1996); *Eli Lilly and Co. v. U.S. Dept. of Health and Human Svcs,* 2021 WL 5039566 at *19 (S.D. Ill. 10/29/2021) (unpublished); *Novartis Pharm. Corp. v. Espinosa,* 2021 WL 5161783 at *6 (D.D.C. 11/05/2021) (unpublished); *Pharm Res. And Mfrs. of Am. v. McClain,* 645 F.Supp.3d 890, 899 (E.D. Ark. 12/12/2022); *Sanofi Aventis U.S. LLC v. U.S. Dept. of Health and Human Svcs.,* 58 F.4th 696, 703-704 (3rd Cir. 2023).

3. The allegations in Paragraph 3 consist of Plaintiffs' characterizations of federal law, characterizations of Congressional actions and intent, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 3 are denied. Answering further, the relevant provisions of the federal 340B statute impose only a price term for drug sales to covered entities, no other terms of the sale are addressed. *See Sanofi Aventis U.S. LLC,* 58 F.4th at 704; *see also Astra USA, Inc. v. Santa Clara County, California,* 563 U.S. 110, 113 (2011) ("[w]e hold that suits by 340B entities *to enforce ceiling-price contracts* running

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between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime" (emphasis added)).

4. The allegations of Paragraph 4 consist of Plaintiffs' characterization of federal law, characterizations of Congressional actions and intent, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 4 are denied. Answering further, the federal 340B statute's provisions regarding diversion are directed to the end users of the drugs, not intermediaries, as any contrary interpretation would render the use of any courier to deliver the drugs to patients, including the U.S. Postal Service, UPS, or FedEx, impermissible. *See Novartis Pharma. Corp.,* 2021 WL 5161783 at *7, n. 3.

5. The allegations in Paragraph 5 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

6. To the extent the allegations in Paragraph 6 assert that contractual arrangements between covered entities and commercial pharmacies did not exist prior to Congress' enactment of the federal 340B statute, they are denied. *See Eli Lilly and Co.,* 2021 WL 5039566 at *11 ("[r]eliance on such arrangements [with contract pharmacies] was a common practice at the time the 340B statute was enacted"). The remaining allegations in Paragraph 6 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

7. To the extent the allegations in Paragraph 7 assert that the federal 340B statute contains no provisions directing the manner by which 340B drugs must be distributed to covered entities or their patients, they are admitted. To the extent the allegations of Paragraph 7 assert that a covered entity's use of a contract pharmacy constitutes an abuse of the 340B program, they are denied. To the extent the allegations of Paragraph 7 address the adoption of policies by drug manufacturers, including Plaintiffs, they are denied for lack of sufficient information to form a

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reasonable belief as to the truth thereof. The remaining allegations of Paragraph 7 consist of characterizations of state and/or federal law and legal conclusions to which no response is required. To the extent further response is deemed necessary, the remaining allegations of Paragraph 7 are denied. Answering further, upon information and belief, Plaintiffs have implemented policies that require covered entities to bear the administrative costs of auditing claims data in order to utilize contract pharmacies, which is contrary to the explicit language of the federal 340B statute. *See* 42 U.S.C. § 256b(a)(5)(C) (requiring manufacturer audits to comply with "procedures established by the Secretary relating to the number, duration, and scope of audits" and for such audits to be at "the manufacturer's expense"); 42 U.S.C. § 256b(d)(2)(B)(iv) (providing for the "establishment of a single, universal, and standardized system" for use by manufacturers, covered entities, and the federal government). Moreover, the policies implemented by various drug manufacturers relating to covered entities' use of contract pharmacies has facilitated abuse of the 340B program by *drug manufacturers,* as reflected by the sharp increase in overcharges to covered entities following the implementation of such policies. *See* 340B Health, "340B Transparency Efforts Uncovering More Drug Company Overcharges." (December 8, 2021).

8. The allegations in Paragraph 8 consist of Plaintiffs' characterizations of certain federal court jurisprudence, characterizations of federal law, characterizations of Congressional actions and intent, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 8 are denied.

9. To the extent Paragraph 9 alleges that Defendant joined in an *amicus curiae* brief on behalf of the State of Louisiana, along with twenty-three other states and the District of Columbia, asserting that other drug manufacturers' internal policies rendered safety-net healthcare providers unable to provide their patients with affordable prescription drugs, these allegations are

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admitted. To the extent the allegations in Paragraph 9 consist of Plaintiffs' characterizations of federal law, characterizations of federal court decisions, and/or conclusions of law, no response is required. To the extent further response is deemed necessary, the remaining allegations in Paragraph 9 are denied.

10. The allegations of paragraph 10 consist of Plaintiffs' characterizations of Louisiana law, the intent of the Louisiana Legislature, and/or conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 10 are denied.

11. The allegations in Paragraph 11 are denied.

12. The allegations in Paragraph 12 consist of Plaintiffs' characterizations of federal law, characterizations of federal court jurisprudence, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 12 are denied. Answering further, Act 358 furthers the purposes and objectives of the federal 340B statute by enabling covered entities to stretch scarce Federal resources as far as possible, allowing them to reach more eligible patients and provide more comprehensive services. *See* H.R. Rep. No. 102-384(II) at *12. Furthermore, Act 358 does not change or conflict with any requirements imposed by the federal 340B statute, as the statute is silent with respect to 340B drug distribution and imposes no requirements with respect thereto. *See* citations in ¶ 2.

13. The allegations in Paragraph 13 consist of Plaintiffs' characterizations of federal law, characterizations of Supreme Court jurisprudence, characterizations of legal arguments advanced by the federal government in other litigation, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 13 are denied. Answering further, Plaintiffs voluntarily offer to sell 340B drugs to certain entities for a specified price, and upon a covered entity's acceptance of Plaintiffs' offer(s), ownership of

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the 340B drugs transfers to the covered entity, even though Plaintiffs have not yet delivered the drugs and the covered entity has not yet paid the sale price. *See* La. Code Civ. Proc. art. 2456; *see also Eli Lilly and Co.,* 2021 WL 5039566 at *21 (denying drug manufacturer's takings claim "due to the fact that they have voluntarily chosen to participate in the 340B program and are thus free to terminate their participation if and when they may choose to do so"). Act 358 therefore prohibits Plaintiffs from refusing or interfering with delivery of 340B drugs *owned by covered entities,* and does not require Plaintiffs to transfer any property owned by them. *See* La. R.S. 40:2882(A) (defining "340B drug" as a drug that has been "purchased" by a covered entity); *Hignell-Stark v. City of New Orleans*, 46 F.4th 317, 322 (5th Cir. 2022), quoting *Phillips v. Wash. Legal Found.*, 524 U.S. 156, 164 (1998) ("[t]he Takings Clause protects property interests, but does not create them"); *Loretto v. Teleprompter Manhattan CATV Corp.,* 458 U.S. 419, 435-437 (1982) ("property" for purposes of a Fifth Amendment takings claim consists of "the group of rights which the so-called ***owner*** exercises in his dominion of the physical thing," such as "the right to possess, use, and dispose of it") (emphasis added). Moreover, "[a]s long as just compensation remedies are available … injunctive relief [on a Fifth Amendment takings claim] will be foreclosed." *Knick v. Twp. of Scott, Pennsylvania,* 139 S.Ct. 2162, 2179 (2019).

14. The allegations in Paragraph 14 consist of Plaintiffs' characterizations of Louisiana law, characterizations of Supreme Court jurisprudence, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 14 are denied. Answering further, Act 358 addresses 340B drugs purchased by covered entities, not those owned by Plaintiffs or any other pharmaceutical manufacturer. *See* La. R.S. 40:2882(1). Furthermore, as the federal 340B statute is silent as to the distribution of 340B drugs, Act 358 does not change any existing requirements dictating when Plaintiffs must provide or deliver 340B drugs

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to covered entities, but rather fills in one of the federal 340B statute's "many gaps." *See Pharma. Res. and Mfrs. Of Am. v. McClain,* 645 F.Supp.3d 890, 899; *Novartis,* 2021 WL 5161783 at *9 (the federal 340B statute "does not compel any particular outcome with respect to covered entities' use of pharmacies").

15. The allegations in Paragraph 15 consist of Plaintiffs' characterizations of Louisiana law and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 15 are denied. Answering further, Act 358 has no effect upon 340B drugs owned by Plaintiffs or any other pharmaceutical manufacturer, and addresses only 340B drugs purchased by covered entities. *See* La. R.S. 40:2882(1). As a result, Plaintiffs' takings claims under Article I, Section 4 of the Louisiana Constitution fail for the same reasons as their takings claims under the Fifth Amendment to the United States Constitution.

16. To the extent the allegations of Paragraph 16 assert the provisions of Act 358 are vague, these allegations are denied. To the extent the allegations of Paragraph 16 consist of Plaintiffs' characterization of Louisiana law, characterizations of federal court jurisprudence, and conclusions of law, no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 16 are denied in their entirety.

17. The allegations in Paragraph 17 are admitted to the extent that Plaintiffs' First Amended Complaint seeks declaratory and injunctive relief; Defendant denies, however, that Plaintiffs are entitled to such relief. To the extent the allegations of Paragraph 17 consist of Plaintiffs' characterizations of this action and/or conclusions of law, no response is required. To the extent a response is deemed necessary, the remaining allegations in Paragraph 17 are denied.

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PARTIES TO THE ACTION

18. The allegations in Paragraph 18 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

19. The allegations in Paragraph 19 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

20. The allegations in Paragraph 20 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

21. The allegations in Paragraph 21 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

22. The allegations in Paragraph 22 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

23. The allegations in Paragraph 23 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

24. The allegations in Paragraph 24 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

25. The allegations in Paragraph 25 are admitted.

JURISDICTION AND VENUE

26. The allegations in Paragraph 26 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 26 are denied.

27. The allegations in Paragraph 27 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 27 are denied.

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28. The allegations in Paragraph 28 consist of conclusions of law to which no response is required. To the extent a response is deemed required, the allegations in Paragraph 28 are denied.

29. Defendant admits the allegations in Paragraph 29 to the extent they assert the existence of offices of the Louisiana Attorney General in the cities of Alexandria, Lafayette, Monroe, and Shreveport. The remaining allegations of Paragraph 29 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

GENERAL ALLEGATIONS

A. The 340B Drug Pricing Program

30. The allegations in Paragraph 30 consist of conclusions of law and Plaintiffs' characterizations of Congress's actions and intent to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 31 are denied.

31. The allegations in Paragraph 31 consist of conclusions of law and Plaintiffs' characterizations of Congressional actions and intent to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 31 are denied.

32. To the extent the allegations in Paragraph 32 address purported actions of pharmaceutical manufacturers, they are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. To the extent the allegations in Paragraph 32 consist of conclusions of law and Plaintiffs' characterizations of Congressional actions and intent, no response is required. To the extent further response is deemed necessary, the allegations in paragraph 32 are denied in their entirety.

33. The allegations in Paragraph 33 consist of Plaintiffs' characterizations of federal statutes and conclusions of law to which no response is required. To the extent a response is

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deemed necessary, the allegations in Paragraph 33 are denied. Answering further, Louisiana law provides that a contract of sale is formed whenever a covered entity accepts Plaintiffs' offer to sell a 340B drug at the specified price. *See* La. Code Civ. Proc. arts. 1927 and 2439.

34. The allegations in Paragraph 34 consist of Plaintiffs' characterizations of federal statutes, characterizations of federal court jurisprudence, and conclusions of law to which no response is required. To the extent a response is deemed required, the allegations in Paragraph 34 are denied. Answering further, the federal 340B statute is silent as to both the method by which 340B drugs are distributed and covered entities' utilization of contract pharmacies. *See Eli Lilly and Co.,* 2021 WL 5039566 at *16 ("[t]he 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations") (emphasis in original); *Novartis Pharma Corp,* 2021 WL 5161783 at *6, quoting *AstraZeneca Pharms.,* 2021 WL 2458063 at *9 ("the [340B] statute does not compel any particular outcome with respect to covered entities' use of pharmacies"); *Sanofi Aventis U.S. LLC,* 58 F.4th at 704 (stating that the federal 340B statute "imposes only a price term for drug sales to covered entities, leaving all other terms blank"); *Pharma Res. and Mfrs. of Am.,* 645 F.Supp. at 899 ("Arkansas's covered entities have filled in this gap [in the federal 340B statute] through contract pharmacy arrangements").

35. The allegations in Paragraph 35 regarding the per unit ceiling prices of certain drugs are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. The remaining allegations in Paragraph 35 consist of Plaintiffs' characterizations of federal law and conclusions of law, to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 35 are denied.

36. The allegations in Paragraph 36 consist of Plaintiffs' characterizations of federal law, characterizations of federal court jurisprudence, and conclusions of law to which no response

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is required. To the extent a response is deemed necessary, the allegations in Paragraph 36 are admitted.

37. The allegations in Paragraph 37 consist of conclusions of law, to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 37 are denied. Answering further, the federal 340B statute required Plaintiffs and other participants in the 340B program to offer 340B drugs for purchase by covered entities without regard to the method used by the covered entity to distribute the drugs to its patients.

38. The allegations in Paragraph 38 regarding the actions of commercial contract pharmacies are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. The remaining allegations in Paragraph 38 consist of conclusions of law, to which no response is required. To the extent a response is deemed required, the allegations in Paragraph 38 are denied. Answering further, both the Pharmaceutical Pricing Agreement ("PPA") between Plaintiffs' and HSRA are structured to prevent pharmaceutical manufacturers participating in the 340B program from selling 340B drugs to covered entities at a higher price than specified in the PPA, regardless of the method used by the covered entity to distribute the 340B drugs to its patients.

39. The allegations in Paragraph 39 pertaining to the actions of pharmaceutical manufacturers are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. The remaining allegations of Paragraph 39 consist of Plaintiffs' characterizations of Supreme Court jurisprudence and conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 39 are denied in their entirety.

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40. The allegations in Paragraph 40 consist of Plaintiffs' characterizations of federal law, characterizations of Congressional actions and intent, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 40 are denied. Answering further, Plaintiffs and all other pharmaceutical manufacturers participating in the 340B program do so voluntarily – in no way are they "forced" to transfer ownership of 340B drugs at the price set forth in their PPA with the federal government. Furthermore, neither the letter nor the spirit of the federal 340B statute reflects any Congressional intent to allow drug manufacturers participating in the 340B program to implement internal policies that result in the sale of 340B drugs to covered entities at prices above those set forth in the PPA based solely upon the method a covered entity uses to distribute 340B drugs to their patients. Such policies are themselves at odds with the purposes and objectives of the 340B program as they reduce access to affordable medications for the patients of covered entities.

41. The allegations in Paragraph 41 consist of Plaintiffs' characterizations of federal statutes and conclusions of law to which no response is required. To the extent a response is deemed necessary, it is admitted that the parenthetical accurately reproduces the language of 42 U.S.C. § 256b(a)(5)(B), but denied that this language prohibits the delivery of drugs purchased by a covered entity to a contract pharmacy as opposed to a covered entity's "resale" of such drugs, as stated in the statute's text. *See Novartis Pharma Corp.,* 2021 WL 5161783 at *7, n. 3 (stating that the reference to "patients" in 42 U.S.C. § 256b(a)(5)(B) "suggests that the concern is transfers to end users of the drug, not intermediaries," that the interpretation advanced by Plaintiffs "would suggest that the use of any courier, including the U.S. Postal Service, UPS, or FedEx, for drug distribution would be impermissible," and that such an interpretation would also "be problematic [for 340B drug manufacturers, like Plaintiffs, that] allow some contract pharmacy use").

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42. The allegations in Paragraph 42 consist of Plaintiffs' characterizations of federal statutes and conclusions of law to which no response is required. To the extent a response is deemed necessary, it is admitted that the heading of 42 U.S.C. § 256b(a)(5)(A) is "Prohibiting duplicate discounts or rebates," but that the language of the Subsection is the best evidence of its contents. Answering further, 42 U.S.C. § 256b(a)(5)(A)(ii) mandates that the Secretary of U.S. Department of Health and Human Services ("HHS") – not drug manufacturers participating in the 340B program – "establish a mechanism to ensure that covered entities comply" with the federal 340B statute's provisions regarding duplicate discounts or rebates.

43. The allegations in Paragraph 43 consist of Plaintiffs' characterizations of federal statutes and conclusions of law to which no response is required. To the extent a response is deemed necessary, the language of 42 U.S.C. § 256b(d)(2)(A) provides the best evidence of its contents. Answering further, the federal 340B statute mandates that the HHS Secretary protect the 340B program's integrity by "provid[ing] for improvements in compliance by manufacturers … in order to prevent overcharges and other violations of the [federal 340B statute's] discounted pricing requirements…" 42 U.S.C. § 256b(d)(1)(A).

44. The allegations in Paragraph 44 consist of Plaintiffs' characterizations of federal statutes and conclusions of law to which no response is required. To the extent a response is deemed necessary, it is admitted that the federal 340B statute authorizes 340B drug manufacturers to conduct, "at their own expense," audits of covered entities' records "that directly pertain to the entity's compliance" with the statute's provisions governing duplicate discounts and rebates and the resale of 340B drugs "with respect to drugs of the manufacturer." *See* 42 U.S.C. §256b(a)(5)(C). It is also admitted that the federal 340B statute provides for the "[s]elective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program…"

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and also directs the HHS Secretary to promulgate regulations for the establishment and implementation of "an administrative process for the resolution of claims by covered entities that they have been overcharged for [340B] drugs" and claims by 340B drug manufacturers, "after the conduct of audits as authorized by subsection (a)(5)(C)" involving violations of the statute's duplicate discount/rebate provisions and/or the resale of 340B drugs. In all other respects, the allegations of Paragraph 44 are denied.

45. The allegations in Paragraph 45 consist of Plaintiffs' characterizations of federal statutes, characterizations of Supreme Court jurisprudence, and conclusions of law to which no response is required. To the extent a response is deemed necessary, it is denied that Defendant has ever attempted to enforce any provision of the federal 340B statute or that a state legislature's enactment of laws governing the distribution of 340B drugs purchased by covered entities within the state to the covered entities' patients amounts to private enforcement of the federal 340B statute, which contains no provisions addressing the distribution or delivery of 340B drugs.

46. The allegations in Paragraph 46 consist of Plaintiffs' characterizations of Supreme Court jurisprudence and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 46 are admitted. Answering further, the 340B statute also provides no private right of action to manufacturers of 340B drugs and explicitly prohibits such manufacturers from adopting policies that require covered entities to purchase 340B drugs at a higher price than set forth in the manufacturers' PPA agreement.

47. The allegations in Paragraph 47 consist of Plaintiffs' characterization of federal law and conclusions of law to which no response is required. To the extent a response is deemed necessary, the language of the referenced provisions of the federal 340B statute is the best evidence of their contents. Answering further, failure to comply with the statutory requirements of the 340B

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program may result in a covered entity's removal from the drug discount program, federal enforcement actions, and potentially the imposition of large civil penalties. *See* 42 U.S.C. §§ 256b(d)(2)(B)(v)(I), (d)(2)(B)(v)(II), and (d)(2)(B)(v)(III).

B. The Growth in Contract Pharmacy Arrangements

48. The allegations in Paragraph 48 consist of Plaintiffs' characterizations of actions undertaken by federal agencies and conclusions of law to which no response is required. To the extent a response is deemed necessary, it is admitted that HRSA has allowed covered entities to use contract pharmacies since the 340B program's inception, and that Plaintiffs and other 340B drug manufacturers "permitted 340B discounted drugs to be shipped to pharmacies under contract with covered entities and treated contract pharmacies the same as in-house pharmacies for over 25 years." *See Pharmaceutical Res. and Mfrs. of Am.,* 645 F.Supp.3d at 897.

49. The allegations in Paragraph 49 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 49 are admitted.

50. The allegations in Paragraph 50 consist of Plaintiffs' characterizations of statements appearing in the Federal Register and conclusions of law to which no response is required. To the extent a response is deemed necessary, it is denied that the Federal Register citation contains any reference to contract pharmacies, the 340B Program, or any guidance issued by HRSA. The referenced materials consist of a "Notice of an extension of a currently approved information collection" issued by the U.S. Department of the Interior's Minerals Management Service on March 10, 2009.

51. The allegations in Paragraph 51 consist of Plaintiffs' characterizations of statements appearing in the Federal Register and conclusions of law to which no response is

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required. To the extent a response is deemed necessary, the allegations in Paragraph 51 are denied and do not accurately reflect the cited contents of the Federal Register.

52. The allegations in Paragraph 52 are denied for lack of sufficient information to form a belief as to the truth thereof. Answering further, the use of contract pharmacies by covered entities increases access to affordable medications for the indigent, individuals lacking an adequate means of transportation, or those who face other obstacles in getting prescriptions filled, consistent with purposes and objectives of the 340b program.

53. The allegations in Paragraph 53 pertaining to the operations of commercial contract pharmacies are denied, as is the allegation that contractual arrangements with pharmacies exist solely in the context of the federal 340B program. *See* 59 Fed. Reg. 25,111 (May 3, 1994) (noting that "[e]ntities often use purchasing agents or contract pharmacies" and the arrangements with contract pharmacies are "a customary business practice"). The remaining allegations of Paragraph 53 consist of Plaintiffs' characterizations of federal and state law and conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 53 are denied in their entirety.

54. The allegations in Paragraph 54 are denied as written. Answering further, with respect to the 340B program, regardless of what "inventory model" is used by a particular pharmacy, in Louisiana all 340B drugs are purchased by a covered entity.

55. The allegations in Paragraph 55 are denied for lack of information sufficient to form a reasonable belief in the truth thereof. Answering further, regardless of what "inventory model" a particular pharmacy uses, in Louisiana all 340B drugs are purchased by a covered entity.

56. The factual allegations in Paragraph 56 are denied for lack of information sufficient to form a reasonable belief as to the truth thereof. To the extent the allegations of Paragraph 56

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contain Plaintiffs' characterizations of documents submitted in other court proceedings, such documents are the best evidence of their contents and no response to these allegations is required. To the extent further response is deemed necessary, the allegations of Paragraph 56 are denied in their entirety. Answering further, regardless of what "inventory model" a particular pharmacy uses, in Louisiana all 340B drugs are purchased by a covered entity.

57. The allegations in Paragraph 57 are denied for lack of information sufficient to form a reasonable belief as to the truth thereof.

58. The allegations in Paragraph 58 contain Plaintiffs' characterizations of Congressional intent in creating the 340B program and the findings of an unidentified study to which no response is required. To the extent a response is deemed necessary, the unidentified study serves as the best evidence of its contents, and the remainder of the allegations in Paragraph 58 are denied.

59. The allegations in Paragraph 59 contain Plaintiffs' characterizations of a governmental report, which report is the best evidence of its contents and therefore no response to the allegations is required. The remaining allegations of Paragraph 59 are denied. To the extent further response is deemed necessary, the allegations in Paragraph 59 are denied in their entirety.

60. The allegations in Paragraph 60 contain Plaintiffs' characterizations of governmental reports, industry reports, and/or scholarly journals to which no response is required. To the extent a response is deemed necessary, the materials cited in Paragraph 60 serve as the best evidence of their contents, and the remaining allegations in Paragraph 60 are denied.

61. The allegations in Paragraph 61 contain Plaintiffs' characterizations of a government report, news articles, and other materials to which no response is required. To the extent a response is deemed necessary, the materials referenced in Paragraph 61 serve as the best

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evidence of their contents, and therefore no response to the allegations is required. To the extent a response is deemed necessary, the allegations in Paragraph 61 are denied. Answering further, when enacting the federal 340B statute, Congress permitted, but did not require, covered entities to pass savings from the program along to uninsured or underinsured patients. *See Eli Lilly and Co.,* 2021 WL 5039566 at * 2.

62. The allegations in Paragraph 62 contain Plaintiff's characterization of correspondence transmitted to a former Congressman and industry publications to which no response is required. To the extent a response is deemed necessary, the referenced correspondence and publication are the best evidence of their contents. Answering further, members of Congress have asked HRSA to institute enforcement actions against pharmaceutical manufacturers, such as Plaintiffs, that unilaterally impose policies that result overcharges to covered entities for 340B drugs. *See* Letter from Charles E. Grassley to Inspector General Christi A. Grimm (May 2, 2022).

63. The allegations in Paragraph 63 contain Plaintiffs' characterizations of certain news articles, which news articles are themselves the best evidence of their contents, characterizations of Congressional intent regarding the "design" of the 340B program, and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 63 are denied.

C. Manufacturer's Response to HRSA's Overreach

64. Defendant admits that Plaintiffs have refused to deliver 340B drugs to contract pharmacies unless covered entities pay more than the mandated 340B price, or agree to Plaintiffs conducting a continual audit of their operations at the covered entities' expense. Defendant denies that Plaintiffs have any lawful right to charge covered entities more for 340B drugs than required under their PPA, and also deny that Plaintiffs can require covered entities to bear the costs of an

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audit for the manufacturer's benefit. Answering further, HRSA has determined that Plaintiffs' policies have directly resulted in Plaintiffs' unlawful overcharging of covered entities for 340B drugs. *See* October 17, 2022 Violation Letter from HRSA to AbbVie, Inc.

65. To the extent the allegations in Paragraph 65 reference unidentified "initiatives" undertaken by Plaintiffs, they are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. Answering further, upon information and belief, Plaintiffs have transmitted correspondence to covered entities stating that Plaintiffs will not deliver 340B drugs purchased by a covered entity to contract pharmacies unless the covered entity pays more than the mandated 340B price, or agrees to allow Plaintiffs to conduct a continual audit of the covered entity's operations at the covered entity's expense.

66. The allegations in Paragraph 66 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. Answering further, Plaintiffs' implementation of its "initiatives" has resulted in Plaintiffs overcharging covered entities for 340B drugs.

67. The allegations in Paragraph 67 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. Answering further, regardless of any "commitments" Plaintiffs have made, their policies regarding contract pharmacies have resulted in overcharging covered entities for 340B drugs.

68. The allegations in Paragraph 68 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof. Answering further, regardless of the results generated by different policies implemented by other manufacturers, Plaintiffs policies and "initiatives" have resulted in Plaintiffs' abuse of the 340B program by overcharging covered entities for 340B drugs.

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D. Litigation in Federal Courts

69. The allegations in Paragraph 69 contain Plaintiffs' characterizations of the knowledge, actions, and beliefs of federal agencies and conclusions of law to which no response is required. To the extent a response is deemed necessary, Defendant admits that the federal 340B statute is silent as to the distribution or delivery of 340B drugs.

70. The allegations in Paragraph 70 contain Plaintiffs' characterization of a legal opinion and report from an agency of the federal government and legal conclusions to which no response is required. To the extent a response is deemed necessary, the referenced opinion and report are the best evidence of their contents Answering further, Defendant admits that the federal 340B statute is silent as to the distribution or delivery of 340B drugs.

71. The allegations in Paragraph 71 are denied for lack of sufficient information to form a reasonable belief in the truth thereof. Answering further, upon information and belief, on October 17, 2022, the federal government sent Plaintiffs correspondence stating that AbbVie's internal policies relating to contract pharmacies had resulted in the manufacturer overcharging covered entities for 340B drugs "in direct violation of the 340B statute."

72. The allegations in Paragraph 72 contain Plaintiff's characterizations of the actions and/or inaction of an agency of the federal government and are denied as written for lack of sufficient information to form a reasonable belief as to the truth thereof. Answering further, upon information and belief, on October 17, 2022, the federal government sent Plaintiffs correspondence stating that AbbVie's internal policies relating to contract pharmacies had resulted in the manufacturer overcharging covered entities for 340B drugs "in direct violation of the 340B statute."

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73. The allegations in Paragraph 73 contain Plaintiffs' characterizations of litigation involving different parties pending before different courts and conclusions of law, and therefore no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 73 are admitted. Answering further, to Defendant's knowledge, the only court to have considered issues involving a state statute regulating the distribution of 340B drugs determined that the statute was not preempted by federal law. *See Pharm. Res. and Mfrs. of Am. v. McClain,* 645 F.Supp.3d 890 (E.D. Ark. 2022). The case is currently on appeal before the Eighth Circuit. *See Pharm. Res. and Mfrs. of Am. v. McClain,* No. 22-3675 (8th Cir.)

74. The allegations in Paragraph 74 are admitted to the extent they reference Defendant's status as a signatory to amicus briefs filed on behalf of the State of Louisiana, twenty-three other states, and the District of Columbia, which briefs asserted that policies implemented by different manufacturers threatened the health and well-being of Louisiana residents and prevented Louisiana's most vulnerable citizens from accessing affordable prescription drugs, they are admitted. Answering further, subsequent to the filing of the amicus briefs referenced in Paragraph 74, HRSA determined that Plaintiffs' internal policies relating to contract pharmacies had resulted in the manufacturer overcharging covered entities for 340B drugs "in direct violation of the 340B statute."

75. The allegations in Paragraph 75 contain Plaintiffs' characterizations of a decision issued by a federal appellate court and conclusions of law, to which no response is required. To the extent a response is deemed necessary, Defendant admits the U.S. Court of Appeals for the Third Circuit issued an opinion in the referenced case on January 30, 2023, but states that the opinion itself is the best evidence of the Third Circuit's decision. Answering further, the Third Circuit's opinion confirmed that the text of the federal 340B statute is "silent about delivery" of

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340B drugs, and "imposes only a price term for drug sales to covered entities, leaving all other terms blank." 58 F.4th at 703-704. The issues before the Third Circuit did not include a state's regulation of the manner by which 340B drugs are distributed.

76. The allegations in Paragraph 76 contain Plaintiff's characterization of a federal appellate court decision and conclusions of law to which no response is required. To the extent a response is deemed necessary, Defendant states that the opinion itself is the best evidence of the appellate court's decision. Answering further, the facts under consideration in *Sanofi-Aventis* did not include any finding by HRSA that the policies of the plaintiff manufacturers had resulted in overcharges to covered entities for 340B drugs "in direct violation of the 340B statute." Nor does the decision address a state's ability to regulate the distribution and delivery of 340B drugs to covered entities located within its borders.

77. The allegations in Paragraph 77 contain Plaintiff's characterization of a federal appellate court decision and conclusions of law to which no response is required. To the extent a response is deemed necessary, Defendant denies the allegations of Paragraph 76 and further states that the opinion itself is the best evidence of the appellate court's decision.

E. The Louisiana Law

78. To the extent the allegations in Paragraph 78 assert that the "Defending Affordable Prescription Drug Costs Act," codified at La. R.S. 40:2881 *et seq.,* was enacted during the 2023 Louisiana Legislative Regular Session, they are admitted. In all other respects, the allegations in Paragraph 78 are denied. Answering further, the Third Circuit did not "uphold" any manufacturer's policy in *Sanofi Aventis* – they determined that HRSA lacked the authority to impose delivery restrictions for 340B drugs because the federal 340B statute is silent with respect to distribution or delivery of 340B drugs.

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79. The allegations in Paragraph 79 consist of Plaintiffs' characterizations of a Louisiana statute and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations of Paragraph 79 are denied. Answering further, as Act 358 regulates the delivery and distribution of 340B drugs, it very clearly does not have "changing the terms of the federal 340B program as its regulatory object" since the 340B program lacks any terms governing delivery or distribution which Act 358 could change.

80. The allegations in Paragraph 80 are denied.

81. The allegations in Paragraph 81 are denied.

82. The allegations in Paragraph 82 are denied.

83. The allegations in Paragraph 83 consist of Plaintiffs' characterizations of Louisiana law and legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations of Paragraph 83 are denied. Answering further, while Paragraph 83 does not identify the statute to which its allegations are directed, Act 358 does not add requirements to the conditions for participating in the federal 340B drug program nor does it establish an enforcement process for violations of the federal 340B statute.

84. The allegations in Paragraph 84 consist of Plaintiffs' characterizations of a Louisiana's statutory law and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations of Paragraph 84 are denied. Answering further, while Paragraph 84 fails to identify the "Chapter" to which its allegations are directed, the term "interfere" has a generally accepted meaning such that a person of ordinary intelligence would be given fair notice of what conduct is forbidden. *See State v. Pickering,* 432 So.2d 1067, 1070 (La. App. 3 Cir. 1983), *writ denied,* 438 So.2d 574 (La. 1983); *see also* La. Civ. Code art. 11.

85. The allegations in Paragraph 85 consist of Plaintiffs' characterizations of a Louisiana statute and conclusions of law to which no response is required. To the extent a response is deemed necessary, the referenced Louisiana statute is the best evidence of what is contained therein.

86. The allegations in Paragraph 86 consist of Plaintiffs' characterizations of Louisiana statutes and conclusions of law to which no response is required. To the extent a response is deemed necessary, the referenced Louisiana statutes are the best evidence of what is contained therein.

87. The allegations in Paragraph 87 consist of Plaintiffs' characterizations of Louisiana statutes and conclusions of law to which no response is required. To the extent a response is deemed necessary, the referenced Louisiana statutes are the best evidence of what is contained therein.

88. The allegations in Paragraph 88 consist of Plaintiffs' characterizations of a Louisiana statute and conclusions of law to which no response is required. To the extent a response is deemed necessary, the referenced statute is the best evidence of what is contained therein.

89. The allegations in Paragraph 89 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 89 are denied. Answering further, Act 358 in no way attempts to regulate the pricing of 340B drugs, which is governed by the federal 340B statute, and the federal 340B statute is silent as to the distribution and delivery of 340B drugs, which is what Act 358 regulates. Just as the federal 340B statute does not prohibit manufacturers from instituting policies regarding delivery and distribution of 340B drugs, so too are states allowed to enact laws guarding against drug manufacturers' refusal to deliver drugs purchased by covered entities, or other activities that place the health, safety, and

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welfare of the states' residents in jeopardy. *See Wyeth v. Levine,* 555 U.S. 555, 574 (2009) ("state law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings").

STANDING

90. To the extent the allegations in Paragraph 90 allege that Plaintiffs have suffered injuries as a result of Act 358, they are denied. The remaining allegations of Paragraph 90 are denied for lack of sufficient information to form a reasonable belief as to the truth thereof.

91. To the extent the allegations in Paragraph 91 allege that Plaintiffs have suffered injuries as a result of Act 358, they are denied. The remaining allegations of Paragraph 91 consist of Plaintiffs' characterizations of federal and state law and conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 91 are denied in their entirety.

92. To the extent the allegations in Paragraph 92 allege that Plaintiffs have suffered injuries as a result of Act 358, including subjection to an action to enforce Act 358 or the imposition of monetary penalties, they are denied. To the extent the allegations of Paragraph 92 assert that Defendant is authorized to bring enforcement actions against drug manufacturers who willfully violate Louisiana law, they are admitted.

93. To the extent the allegations in Paragraph 93 allege that Plaintiffs have suffered injuries as a result of Act 358, they are denied. The remaining allegations of Paragraph 93 consist of conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 93 are denied in their entirety.

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BASIS FOR INJUNCTIVE RELIEF

94. The allegations in Paragraph 94 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 94 are denied.

95. To the extent the allegations in Paragraph 95 assert that Act 358 has caused irreparable harm to Plaintiffs, they are denied. The remaining allegations in Paragraph 95 consist of conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 95 are denied in their entirety.

96. To the extent the allegations in Paragraph 96 assert that Act 358 prohibits drug manufacturers from performing any activity mandated by federal law, they are denied. The remaining allegations of Paragraph 96 consist of conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations in Paragraph 96 are denied in their entirety. Answering further, there is no express preemption provision in the federal 340B statute and case law involving principles of express preemption are therefore wholly inapplicable. In addition, there are no circumstances under which a pharmaceutical's compliance with Act 358 would require the manufacturer to violate the federal 340B statute.

97. To the extent the allegations in Paragraph 97 assert that Act 358 could result in compensable damages to Plaintiffs in an amount equal to all purchases made under the 340B program, they are denied. The remaining allegations in Paragraph 97 consist of conclusions of law to which no response is required. To the extent further response is deemed necessary, the allegations of Paragraph 97 are denied in their entirety. Answering further, to the extent the damages alleged in Paragraph 97 refer to losses associated with duplicate discounts or diversion, HRSA's ADR process is the exclusive method to claim such damages. *See Pharm. Res. and Mfrs.*

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of Am. v. Mclain, 645 F.Supp.3d at 900 ("[t]here can be no dispute that Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal court").

98. The allegations in Paragraph 98 are denied. Answering further, Plaintiffs do not have a constitutional right to adopt internal policies that result in overcharging covered entities for 340B drugs, or that allow Plaintiffs to refuse to deliver 340B drugs purchased by covered entities.

99. The allegations in Paragraph 99 are denied. Answering further, the federal government has previously determined that the specific policies implemented by Plaintiffs have resulted in Plaintiffs overcharging covered entities for 340B drugs in direct violation of the federal 340B statute. The State of Louisiana has a legitimate interest in ensuring the patients of covered entities have access to affordable prescription drugs and that drug manufacturers do not seek to increase their profits through means that endanger the health, safety, and welfare of Louisiana residents.

100. The allegations in Paragraph 100 are denied. Answering further, as the federal government has previously determined, Plaintiffs' policies directly result in covered entities being overcharged for 340B drugs in direct violation of the federal 340B statute. It is not in the public interest to allow pharmaceutical manufacturers to implement policies that unlawfully increase their profits at the expense of safety-net institutions and the health, safety, and welfare of Louisiana's most vulnerable citizens.

FIRST CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Federal Preemption Under the Supremacy Clause, U.S. Const. art. VI, cl. 2

101. Defendant re-asserts and incorporates by reference the responses to Paragraphs 1 – 100 appearing above as though set forth fully herein.

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102. The allegations in Paragraph 102 consist of Plaintiffs' abbreviated citation of constitutional provisions and conclusions of law to which no response is required. To the extent a response is deemed necessary, the Constitution of the United States is the best evidence of what is contained therein.

103. To the extent the allegations in Paragraph 103 assert the existence of an express preemption clause in the federal statutory scheme governing the 340B program, they are denied. The allegations in Paragraph 103 also consist solely of legal conclusions to which no response is required. To the extent further response is deemed necessary, Defendant denies that Act 358 is either expressly or impliedly preempted.

104. The allegations in Paragraph 104 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 104 are denied.

105. The allegations in Paragraph 105 are denied. The 340B program is not comprehensive and consists only of three basic parts: (1) a cap on drug makers' prices, (2) restrictions on covered entities, and (3) compliance mechanisms. *See Sanofi Aventis,* 58 F.4th at 699. The 340B program is also tied to the earlier-enacted, much larger Medicaid Drug Rebate Program, which requires states to enter into agreements with the federal government and enact their own regulatory schemes to participate in the program. *See Astra USA, Inc. v. Santa Clara County, Cal.,* 563 U.S. 110, 114 (2011); 42 U.S.C. § 1396a. Moreover, if Congress thought state regulation posed an obstacle to the 340B program's objectives, "it surely would have enacted an express pre-emption provision at some point" in the 340B program's 30+ year history. *See Wyeth v. Levine,* 555 U.S. 555, 574 (2009). The lack of Congressional intent to displace state regulation of 340B drug manufacturers reflects a determination that regulation by the states furthers consumer

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protection by motivating manufacturers to act in the best interest of the individuals and entities that purchase their drugs. *Id.*

106. The allegations in Paragraph 106 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 106 are denied. Answering further, Congress' silence on the issue of preemption is "powerful evidence" that Congress did intend HRSA oversight to be the exclusive means of ensuring the availability of 340B drugs to covered entities. *Wyeth,* 555 U.S. at 575. Act 358 does not change any requirements for Plaintiffs' participation in the federal 340B program, but merely prevents participating manufacturers from abusing the program through the implementation of measures designed to increase profits at the expense of covered entities and their patients.

107. The allegations in Paragraph 107 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 107 are denied. Answering further, the federal 340B statute is silent regarding the role contract pharmacies have in the 340B program, and "[w]hen a statute does not include even a single reference to the pertinent word (e.g. "pharmacy"), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word," thus precluding a finding of field preemption. *See Pharm. Res. and Mfrs. of Am.,* 645 F.Supp.3d at 899, quoting *AstraZeneca Pharms. LP v. Becerra,* 543 F.Supp.3d 47, 59 (D. Del. 2021). Moreover, the question for impossibility pre-emption is whether the private party could independently do under federal law what state law requires of it. *See PLIVA, Inc. v. Mensing,* 564 U.S. 604, 620 (2011), citing *Wyeth,* 555 U.S. at 573. Here, Act 358 merely requires 340B drug manufacturers to deliver 340B discounted drugs purchased by covered entities to contract pharmacies – a practice Plaintiffs and other 340B drug manufacturers voluntarily engaged in for more than 25 years before implementing

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internal policies that sought to end the practice. *See Pharm Res. and Mfrs. of Am.,* 645 F.Supp.3d at 897. Thus, there is clearly no argument that it would impossible for Plaintiffs to comply with both Act 358 and the federal 340B statute.

108. The allegations in Paragraph 108 consist of Plaintiffs' characterizations of state and federal laws and conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 108 are denied. Answering further, Act 358 does not purport to grant Defendant any role in the federal 340B program, nor any authority to enforce the federal 340B statute. The law regulates the distribution and delivery of 340B drugs purchased by Louisiana covered entities – matters on which the federal 340B statute is silent. State regulation of matters outside the purview of the federal regulatory scheme in no way obstructs or interferes with Congress' objectives in enacting the federal 340B statute, and clearly cannot conflict with federal requirements that do not exist.

109. The allegations in Paragraph 109 constitute conclusions of law to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 109 are denied. Answering further, Congress did not grant the Secretary of HHS authority to administer or impose requirements regarding the distribution or delivery of 340B drugs. *See e.g. Sanofi Aventis,* 58 F.4th at 703-705; *Pharm. Res. and Mfrs. of Am.,* 645 F.Supp.3d at 899; *Eli Lilly and Co.,* 2021 WL 5039566 at * 17-19. States are therefore free to fill in the gaps Congress left in the statutory scheme governing the 340B program. *See Pharm. Res. and Mfrs. of Am.,* 645 F.Supp.3d at 899.

110. The allegations in Paragraph 110 constitute conclusions of law to which no response is required. To the extent a response is deemed required, the allegations in Paragraph 110 are denied. Answering further, Act 358 does not force Plaintiffs or any other 340B drug

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manufacturer to transfer "their drugs" to anyone – it requires them to deliver 340B drugs "purchased by a covered entity" to the pharmacies charged with dispensing such drugs to the covered entity's patients. *See* La. R.S. 40:2882(1). As federal law does not address, let alone require, any particular action with respect to the distribution and delivery of 340B drugs, there is simply no provision of federal law that could arguably preempt Act 358.

SECOND CLAIM FOR RELIEF

(In the Alternative)
Prospective Injunctive Relief and Declaratory Relief –
Violation of Takings Clause, U.S. Const. art. I, § 10, cl. 1

111. Defendant re-asserts and incorporates by reference the responses to Paragraphs 1 – 110 appearing above as though set forth fully herein.

112. The allegations in Paragraph 112 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the Constitution of the United States is the best evidence of what is contained therein.

113. The allegations in Paragraph 113 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 113 are denied. Answering further, while the meaning of "property" for purposes of a Fifth Amendment takings claim is a federal question, the answer and precise dimensions of a property interest are normally determined by reference to local law. *United States v. 0.073 acres of land, more or less, situated in Pars. of Orleans & Jefferson, Louisiana,* 705 F.3d 540, 544 (5th Cir. 2013), quoting *United States ex rel. Tenn. Valley Auth. v. Powelson,* 319 U.S. 266, 279 (1943); *Ruckelshaus v. Monsanto Co.,* 467 U.S. 986, 1001 (1984). Thus, the Takings Clause protects property interests but does not create them. *See Hignell-Stark v. City of New Orleans*, 46 F.4th 317, 322 (5th Cir. 2022), quoting *Phillips v. Wash. Legal Found.*, 524 U.S. 156, 164 (1998). As a result, the

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determination of the existence or absence of a property interest under state law is usually dispositive of a Fifth Amendment takings claim. *Id.* at 323 (citations omitted).

114. The allegations in Paragraph 114 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 114 are denied. Answering further, the U.S. Supreme Court has a longstanding recognition that property consists of "the group of rights which the so-called ***owner*** exercises in his dominion of the physical thing," such "as the right to possess, use, and dispose of it." *Id.* at 169-170 (emphasis added), quoting *Loretto v. Teleprompter Manhattan CATV Corp.,* 458 U.S. 419, 435-437 (1982); *States v. General Motors Corp.,* 323 U.S. 373, 359 (1945). Thus, an ***owner*** of property has an actionable Fifth Amendment takings claim as soon as the government takes his property without paying for it. *Knick v. Township of Scott, Pennsylvania,* 139 S. Ct. 2162, 2170 (2019). Even so, the Fifth Amendment's Takings Clause cannot serve as the basis for enjoining a state's regulatory scheme when just compensation remedies are available. *Id.* at 2179.

115. The allegations in Paragraph 115 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 115 are denied.

116. The allegations in Paragraph 116 are denied. Answering further, Act 358 does not require Plaintiffs or any other drug manufacturer to take any action with respect to property they own, and does not require the sale of any drug at a particular price. By its explicit terms, Act 358 prohibits Plaintiffs and other drug manufacturers from denying, restricting, prohibiting, or otherwise interfering with the acquisition and delivery of 340B drugs "purchased by a covered entity" which, according to Louisiana law, are *owned* by the covered entity. *See* La. R.S. 40:2882(1); La. R.S. 40:2884; La. Code Civ. P. art. 2456. As with all pharmaceutical

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manufacturers participating in the 340B program, Plaintiffs have voluntarily entered into agreements with the federal government to offer their 340B drugs to covered entities for purchase at a specified price. Upon a covered entity's acceptance of Plaintiffs' offer(s), ownership of the 340B drugs immediately transfers to the covered entity, even though the drugs have not yet been delivered and the covered entity has not yet paid the sale price. *See* La. Code Civ. Proc. art. 2456. As a result, Act 358 only regulates Plaintiffs' distribution and delivery of 340B drugs that are *owned* by Louisiana covered entities; it imposes no requirements upon Plaintiffs to take any action with respect to drugs that are *owned* by them. *Id.; see also Eli Lilly and Co.,* 2021 WL 5039566 at *21 (denying drug manufacturer's takings claim "due to the fact that they have voluntarily chosen to participate in the 340B program and are thus free to terminate their participation if and when they may choose to do so").

117. The allegations in Paragraph 117 are denied. Answering further, Act 358 only regulates 340B drugs purchased by a covered entity and does not regulate any property owned by Plaintiffs or other drug manufacturers.

118. The allegations in Paragraph 118 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 118 are denied.

119. The allegations in Paragraph 119 are denied. Answering further, Act 358 does not require Plaintiffs or any other drug manufacturer to "transfer *their* drugs to commercial pharmacies" as alleged in Paragraph 119, but instead prohibits Plaintiffs from refusing to deliver 340B drugs *purchased by covered entities* to the pharmacies responsible for dispensing the drugs to the covered entities' patients.

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THIRD CLAIM FOR RELIEF

Prospective Injunctive Relief and Declaratory Relief – Violation of the Right to Property, La. Const. Ann. Art. I, § 4.

120. Defendant re-asserts and incorporates by reference the responses to Paragraphs 1 – 119 appearing above as though set forth fully herein.

121. The allegations in Paragraph 121 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the Louisiana Constitution is the best evidence of what is contained therein.

122. The allegations in Paragraph 122 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 122 are denied.

123. The allegations in Paragraph 123 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 123 are denied.

124. The allegations in Paragraph 124 are denied. Answering further, Article I, Section 4(A) of the Louisiana Constitution provides that "[e]very person has the right to acquire, own, control, use, enjoy, protect, and dispose of private property. This right is subject to reasonable statutory restrictions and the reasonable exercise of the police power." Act 358 does not affect any taking of Plaintiffs' property, but rather ensures the rights of covered entities to acquire, control, use, and dispose of *their* property – i.e. 340B drugs purchased from manufacturers like Plaintiffs – by prohibiting 340B drug manufacturers from acting in a manner that endangers the health, safety, and welfare of Louisiana citizens. The states' core police powers have always included the authority to protect the health, safety, and welfare of their citizens. *See Brecht v. Abrahamson,* 507 U.S. 619, 635 (1993); *Carver v. Louisiana Dep't of Pub. Safety,* 2017-1340 (La.

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1/30/18), 239 So.3d 226, 231, quoting *State v. Golston,* 2010-2804 (La. 7/1/11), 67 So.3d 452, 466 ("[g]overnments have an inherent need 'to protect the safety and welfare of their citizens from the unrestrained liberty of some individuals'").

125. The allegations in Paragraph 125 consist of legal conclusions to which no response is required. To the extent a response is deemed necessary, the allegations in Paragraph 125 are denied. Answering further, Act 358 does not require Plaintiffs or any other manufacturer to transfer property they own to the government or any third party. To the contrary, Act 358 only regulates Plaintiffs' actions in connection with drugs they have already voluntarily sold to a covered entity at the federally-mandated price to which Plaintiffs voluntarily agreed in their PPA with HRSA.

126. The allegations of Paragraph 126 are denied. Answering further, Act 358 does nothing more than prevent pharmaceutical manufacturers like Plaintiffs from purposely interfering with the distribution and delivery of 340 drugs sold to covered entities. Plaintiffs have no legally cognizable interest in implementing measures designed to increase their profits at the expense of the health, safety, and welfare of Louisiana's citizens.

FOURTH CLAIM FOR RELIEF

Declaratory/Injunctive Relief – Due Process Clause, U.S. Const. art. XIV

127. Defendant re-asserts and incorporates by reference the responses to Paragraphs 1 – 126 appearing above as though set forth fully herein.

128. The allegations in Paragraph 128 consist of conclusions of law to which no response is required. To the extent a response is deemed necessary, the Constitution of the United States is the best evidence of what is contained therein.

129. The allegations in Paragraph 129 consist of legal conclusions to which no response

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is required. To the extent a response is deemed necessary, the allegations in Paragraph 129 are denied.

130. The allegations in Paragraph 130 are denied. Answering further, the term "interfere" has a generally accepted meaning such that a person of ordinary intelligence would be given fair notice of what conduct is forbidden. *See State v. Pickering,* 432 So.2d 1067, 1070 (La. App. 3 Cir. 1983), *writ denied,* 438 So.2d 574 (La. 1983); *see also* La. Civ. Code art. 11. Moreover, the provisions of Act 358 provide numerous examples of the type of "interference" that is prohibited under the law, including "deny[ing], restrict[ing], or prohibit[ing]" the acquisition or delivery of 340B drugs by pharmacies contracted to a covered entity (La. R.S. 40:2884(A)); the placement of "additional requirements, restrictions, or unnecessary burdens" resulting in administrative costs or fees to a covered entity (La. R.S. 40:2883(A)(1)(d)); and the "creation of a restriction or additional charge on a patient who chooses to receive drugs" from a covered entity (La. R.S. 40:2883(A)(1)(e)). *See also* La. Code Civ. P. arts. 11 ("[t]he words of a law must be given their generally prevailing meaning") and 13 ("[l]aws on the same subject matter must be interpreted in reference to each other").

131. The allegations in Paragraph 131 are denied. Answering further, the Third Circuit's decision in *Sanofi Aventis* did not consider Plaintiffs' policies, nor did it find that policies that result in overcharging covered entities for 340B drugs are lawful under the federal 340B statute. The Third Circuit's decision did, however, determine that the federal 340B statute "is silent about delivery" of 340B drugs, opening the door for states to enact legislation to fill in the gaps left by the federal legislation governing the 340B program.

132. The allegations in Paragraph 132 contain Plaintiffs' characterization of Louisiana statutes and conclusions of law to which no response is required. The remaining allegations in

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Paragraph 132 are denied. To the extent further response is deemed necessary, the allegations in Paragraph 132 are denied in their entirety. Answering further, the allegations of Paragraph 132 effectively demonstrate that Plaintiffs are not only capable of determining, but are in fact currently aware of the scope of Act 358's prohibitions.

133. The allegations in Paragraph 133 are denied.

PRAYER FOR RELIEF

The remaining Paragraphs of Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief consist of a Prayer for Relief, to which no response is required. To the extent a response is deemed necessary, the allegations contained in the Prayer for Relief are denied and Defendant further denies that Plaintiffs are entitled to any relief.

DEFENDANT'S AFFIRMATIVE DEFENSES

AND NOW, in further response to Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief, Defendant Landry asserts the following Affirmative Defenses:

134. Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief does not state a claim or cause of action sufficient to challenge the constitutionality of Louisiana's Defending Affordable Prescription Drug Costs Act, La. R.S. 40:2881 *et. seq*.

135. Plaintiffs do not assert they have been subjected to any action to enforce the provisions of Louisiana's Defending Affordable Prescription Drug Costs Act, La. R.S. 40:2881 *et. seq*., and thus fail to state a cause of action for which relief can be granted.

136. Plaintiffs' First Amended Complaint does not allege any actual or imminent concrete or particularized injury, and Plaintiffs therefore lack Article III standing to pursue their claims.

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137. Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief fails to sufficiently allege any harm that has resulted from the operation or application of Louisiana's Defending Affordable Prescription Drug Costs Act, La. R.S. 40:2881 *et. seq*., and the Court therefore lacks jurisdiction over the constitutional challenge to Louisiana's statutory law.

138. Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief fails to establish subject matter jurisdiction under the provisions of 28 U.S.C. § 1332.

139. This Court lacks subject matter jurisdiction to order the remedies requested by Plaintiffs.

140. Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief does not allege facts

141. Plaintiffs' claims are barred in whole or in part by applicable state and federal immunities, including but not limited to sovereign immunity, statutory immunity, and/or Eleventh Amendment immunity.

142. Plaintiffs First Amended Complaint for Declaratory and Injunctive Relief fails to join indispensable parties in the causes of action asserted therein.

WHEREFORE, Defendant Jeff Landry, in his official capacity as Attorney General of the State of Louisiana, respectfully prays that this answer be deemed good and sufficient, and after due proceedings have been conducted, that judgment be entered in his favor and against Plaintiffs, dismissing all claims asserted in Plaintiffs' First Amended Complaint for Declaratory and Injunctive Relief with prejudice, at Plaintiffs' sole cost and expense, and awarding Defendant Landry all other relief to which he is entitled under the premises.

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Respectfully submitted,

JEFF LANDRY
LOUISIANA ATTORNEY GENERAL

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Counsel for Defendant, Jeff Landry, in his official capacity as Attorney General of Louisiana

CERTIFICATE OF SERVICE

I hereby certify that on November 22, 2023, the foregoing Answer and Affirmative Defenses was electronically filed with the Clerk of Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

s/ Terrence J. Donahue, Jr.
Terrence J. Donahue, Jr.